

Safe Online Drug Act (SODA)
Congressman Greg Walden & Congressman Jim Davis
Frequently Asked Questions

1) Why is the Safe Online Drug Act important?

Patients need confidence that the medications they purchase online are as safe and effective as those purchased at a neighborhood pharmacy. The Internet is an increasingly important channel for purchasing prescription drugs, and online pharmacies are serving a growing number of consumers. But web-based pharmacies represent a largely unregulated domain. Legitimate pharmacies operate under a broad set of standards, but these standards are all voluntary. While most Internet pharmacies don't sell addictive narcotics to minors or peddle counterfeit prescriptions to unsuspecting seniors, many unscrupulous retailers are more motivated to cut corners on safety to make a quick buck.

There are an alarming number of bad actors posing as legitimate online pharmacies, confusing U.S. consumers and providing them with unsafe and illegal prescription drugs. These web sites often have no pharmacists on staff and bypass the doctor-patient relationship in order to provide medications without a valid prescription. Indeed, some sites brazenly advertise that no prescription is required to purchase medicines. Others simply require a consumer to respond to a brief questionnaire and then a "doctor" provides a "prescription" for a requested drug. By failing to require a prescription, health history and/or physical exam, rogue pharmacies are placing consumer health at risk

According to a report released on June 16, 2004, by the General Accounting Office (GAO), investigators posing as patients were required to produce a prescription for only five of the 29 U.S.-based Internet pharmacies used to compile the report. Twenty-one foreign Internet pharmacies issued prescriptions based on their own medical questionnaires or had no prescription requirements. Four foreign pharmacies sent investigators counterfeit prescriptions. A shipment of the drug OxyContin was shipped in a plastic compact disc case, and a bottle of the AIDS medication Crixivan was packaged in a sealed aluminum can enclosed in a box labeled "Gold Dye and Stain Remover Wax." In short, the GAO report irrefutably established that the American public is at great risk as a result of the lack of safety and efficacy standards to regulate online drug purchases.

2) In an effort to protect consumers, will this legislation limit foreign sources for their medications such as less expensive Canadian drugs?

The Safe Online Drug Act would make no change to the current federal law concerning importations of prescription medications from abroad. Rather, it seeks to establish consistency in the safety and efficacy standards between online prescription drug sales and drug purchases made at local drugstores. In the coming years if the federal government deems the importation of foreign pharmaceuticals to be safe, the SODA will have already established a certification framework that would ensure that foreign Internet

pharmacies abide by the same safety and quality assurance standards as U.S.-based Internet pharmacies.

3) What kind of problems/issues will this legislation address?

This legislation will help ensure that online pharmacies:

- are certified by the FDA. Licensed pharmacies are inspected on a regular basis and require licensed pharmacy personnel. Only about 15 online pharmacies are certified by the National Association of Boards of Pharmacy, the association representing the state organizations, who are currently responsible for licensure.
- adequately protect personal and financial information.
- make contact information available to allow consumers to ask questions and lodge complaints
- safeguard public health by requiring a prescription, health history and/or physical exam before dispensing medications and require that only licensed pharmacists can dispense prescriptions
- inform consumers of the potentially adverse effects of certain drugs if taken without proper medical supervision. These drugs have special safety restrictions on how they are distributed to the public. Additionally, drugs purchased from foreign pharmacies are not subject to FDA-regulated manufacturing controls or FDA inspection of manufacturing facilities.

4) How many Americans currently use the Internet to purchase prescription drugs?

According to Jupiter Research, up to 4.1 million Americans purchased prescription drugs via the Internet in 2003. There are some 450 web sites that claim to sell drugs online, based on a simple search on one of the more popular search engines. Americans spent about \$1.1 billion on re-imported drugs in 2003, according to IMS Health Inc., which tracks prescription trends. Without establishing standards, any problems that currently exist will only become exacerbated as more Americans turn to the Internet to buy their medications.

5) If the Safe Online Drug Act becomes law, how will consumers know that an online pharmacy has been certified by the FDA? What certification standard will be used?

Today consumers have no reliable way to tell which web sites are legitimate and which are not. SODA seeks to remedy this problem by creating a uniform standard and allowing consumers to easily identify which sites are reputable and FDA certified. Already a small percentage of Internet pharmacies voluntarily adhere to the criteria of the Verified Internet Pharmacy Practice Sites (VIPPS) program, which was created by the National Association of Boards of Pharmacy (NABP). The SODA certification standards are closely modeled after the VIPPS program. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal

must have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

Under SODA, all U.S.-based web sites would be required to abide by VIPPS criteria and display an easily identifiable certification seal attesting to the safety of the site.